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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte AVI AVRAMOFF and VALERIE AZOULAY

Appeal 2011-005221
Application 10/575,809
Technology Center 1600

Before TONI R. SCHEINER, MELANIE L. McCOLLUM, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a lansoprazole administration method. The Examiner has rejected the claims on appeal as obvious and lacking written description. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 26-32, 34, 36-42, 44, 46, 47, 49, 50, 58, and 59 are on appeal (App. Br.¹ 2).^{2,3} The claims subject to each rejection have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 27 is representative and reads as follows:

27. A method for administering a therapeutically effective amount of lansoprazole to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof as sole pharmaceutically active ingredient, wherein said substrate is characterized in that said substrate does not include an alkaline agent;

(b) a subcoating layer for coating said substrate, said subcoating layer comprising an alkaline agent comprising sodium stearate; and

(c) an enteric coating material layered over said subcoating layer.

Claims 26-32, 34, 36-40, 42, 44, 46, 47, 49, 50, 58, and 59 stand rejected under 35 U.S.C. § 103(a) as obvious over Depui et al. (WO 96/24375 A1, Aug. 15, 1996) (hereinafter “Depui '375”) in view of Lundberg et al. (EP 1,174,136 A2, Jan. 23, 2002) and Edgren et al. (US 6,210,712 B1, Apr. 3, 2001) (Ans. 4).

¹ Revised Appeal Brief dated September 23, 2010.

² Claims 1-6, 8, 10-16, 18, 20, 21, 23-25, and 51-57 are also pending but have been withdrawn from consideration (App. Br. 2).

³ In addition to the rejections set forth below, claims 39 and 40 are objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form (Ans. 12). However, as noted by the Examiner (*id.* at 18), an objection is not appealable and is therefore not addressed herein.

Claims 26-32, 34, 36-42, 44, 46, 47, 49, 50, 58, and 59 stand rejected under 35 U.S.C. § 103(a) as obvious over Depui '375 in view of Lundberg, Edgren, and Napper et al. (US 2002/0150618 A1, Oct. 17, 2002) (Ans. 7).

Claims 26-32, 34, 36, 38-42, 44, 46, 47, 49, 50, 58, and 59 stand rejected under 35 U.S.C. § 103(a) as obvious over Depui et al. (US 2002/0155153 A1, Oct. 24, 2002) (hereinafter “Depui '153”) in view of Lundberg and Edgren (Ans. 8).

Claims 26-32, 34, 36-42, 44, 46, 47, 49, 50, 58, and 59 stand rejected under 35 U.S.C. § 103(a) as obvious over Depui '153 in view of Lundberg, Edgren, Depui '375, and Napper (Ans. 11).

Claims 26-32, 34, 36-42, 44, 46, 47, 49, 50, 58, and 59 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 12).

OBVIOUSNESS

The Examiner rejects representative claim 27 as obvious over four combinations of references, each of which includes at least one of Depui '375 and Depui '153, together with Lundberg and Edgren. Appellants argue that the “characterizing feature of the formulation of the present invention is that the substrate is devoid of an alkaline agent, while an alkaline agent [sodium stearate] is provided in the separating layer,” and that the applied references “do not teach this feature” (App. Br. 8-9 (emphasis omitted)).

Issue

Does the evidence support the Examiner's conclusion that it would have been obvious to include sodium stearate in the separating layers of Depui '375 and Depui '153?

Findings of Fact

1. The Specification discloses: "The formulation of the present invention contains lansoprazole, preferably in the form of lansoprazole base. The formulation preferably features a substrate comprising lansoprazole (preferably in the base form), without any alkaline agent; a subcoating layer containing alkaline agent; and an enteric coating layer." (Spec. 3: 5-8.)

2. The Specification also discloses: "Preferably, the alkaline agent in the subcoating layer comprises an organic basic salt. More preferably, the organic basic salt includes . . . sodium stearate." (*Id.* at 6: 4-5.)

3. The Depui references both disclose enteric coated tablets including an acid susceptible proton pump inhibitor, such as lansoprazole (Depui '375, pp. 3 & 8; Depui '153, ¶¶ [0014] & [0040]).

4. The Depui references also disclose that "[s]eeds layered with the acid susceptible proton pump inhibitor, optionally mixed with alkaline substances, can be used as the core material" (Depui '375, p. 13; Depui '153, ¶ [0052]).

5. In addition, the Depui references disclose that, "[b]efore applying the enteric coating layer(s) onto the core material . . . , the pellets may optionally be covered with one or more separating layer(s) comprising

pharmaceutical excipients optionally including alkaline compounds” (Depui '375, p. 14; Depui '153, ¶ [0060]).

6. The Depui references also discloses that “[a]dditives such as plasticizers, colorants, pigments, fillers anti-tacking and anti-static agents, such as for instance magnesium stearate, titanium dioxide, talc and other additives may also be included into the separating layer(s)” (Depui '375, p. 15; Depui '153, ¶ [0061]).

7. In addition, the Depui references exemplify tablets containing lansoprazole (Depui '375, pp. 28-29; Depui '153, ¶ [0110]).

8. Lundberg discloses an “oral pharmaceutical dosage form comprising a core material that contains a proton pump inhibitor . . . having a water soluble separating layer and an enteric coating layer” (Lundberg, Abstract).

9. Lundberg discloses: “[T]he active substance is mixed with . . . components to obtain preferred handling and processing properties. . . . Pharmaceutical constituents such as fillers, binders, lubricants, disintegrating agents, surfactants and other pharmaceutically acceptable additives, can be used.” (*Id.* at ¶ [0032].)

10. In addition, Lundberg exemplifies tablets containing lansoprazole and magnesium stearate (*id.* at ¶¶ [0038]-[0039]).

11. Edgren also relates to a drug dosage form (Edgren, Abstract).

12. Edgren discloses that “[t]ypical lubricants comprise a member selected from the group consisting of sodium stearate, potassium stearate, magnesium stearate . . .” (*id.* at col. 8, ll. 7-9).

Analysis

Appellants argue that sodium stearate and magnesium stearate “cannot be considered functionally equivalent as alkalinizing agents” (App. Br. 9). We are not persuaded. The Examiner’s position is not that it would have been obvious to include sodium stearate as an alkalinizing agent. Instead, the Examiner’s position is that it would have been obvious to include sodium stearate as a lubricant (Ans. 10 & 15) and that sodium stearate is inherently an alkaline agent, as disclosed in the Specification (Finding of Fact (FF) 2). Appellants have not adequately explained why this position is incorrect.

Appellants also argue that “the active ingredient of the present invention is preferably the base of lansoprazole, whereas Depui '375 discloses the magnesium salt of omeprazole, which is significantly more stable than the base form, and thus does not require an alkalinizing agent for stabilization” (App. Br. 12). We are not persuaded. We note initially that Appellants specifically indicate that the claims are argued as a group (App. Br. 7, 13, & 15) and that claim 27 encompasses salts of lansoprazole. Moreover, the Depui references clearly disclose a composition containing lansoprazole itself, that is, not in a salt form (FF 7).

Conclusion

The evidence supports the Examiner’s conclusion that it would have been obvious to include sodium stearate in the separating layers of Depui '375 and Depui '153. We therefore affirm the obviousness rejections.

WRITTEN DESCRIPTION

The Examiner finds that the Specification “does not have support for formulations in which lansoprazole is the ‘sole active ingredient’” (Ans. 13). Appellants argue that “the limitation of ‘sole pharmaceutically active ingredient’ in relation to lansoprazole is both implicitly and inherently support[ed] in the present application” (App. Br. 17). We conclude that Appellants have the better position. In particular, we do not find that the Examiner has provided adequate basis for concluding that Appellants’ Specification exemplifies compositions containing an ingredient other than lansoprazole that, in the context of an oral dosage form, would have been considered a “pharmaceutically” active ingredient. We therefore reverse the written description rejection.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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